K021325
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MAY 07 2002

510(k) Summary of Safety and Effectiveness

Date: April 19, 2002

Submitter: GE Medical Systems *Information Technologies*
8200 West Tower Avenue
Milwaukee, WI 53223 USA

Contact Person: Joelle Neider
Regulatory Affairs Specialist
GE Medical Systems *Information Technologies*
Phone: 203-949-8232
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Device: Trade Name: ApexPro Telemetry System

Common/Usual Name: Telemetry Monitoring System

Classification Names:
21 CFR 870.1025 Detector and Alarm, Arrhythmia
21 CFR 870.2910 Transmitters & Receivers, Physiological Signal, Radio Frequency

Predicate Device: K000779 ApexPro Telemetry System

Device Description: The ApexPro Telemetry System is composed of six major components:

- The patient worn data acquisition transmitters
- The receiver antenna system infrastructure
- The receivers
- The receiver subsystem
- A computer platform running the ApexPro Telemetry Application
- A computer platform running a central station application (which may be the same computer platform running the ApexPro Telemetry Application)

Intended Use: The ApexPro Telemetry System is intended for use under the direct supervision of a licensed healthcare practitioner. The system is designed to acquire and monitor physiological data for ambulating patients within a defined coverage area. The system processes this physiological data to detect various ECG arrhythmia events and select physiological parameter limit violations.

The ApexPro Telemetry System is intended to be installed in the hospital or clinical environment in order to provide clinicians with patient physiological data, while allowing for patient mobility. These systems are typically deployed in sub acute care areas in hospitals or clinical sites where patient mobility can enhance the effectiveness of the medical procedures administered.

The physiological parameters monitored include ECG, non-invasive blood pressure and SpO_2. The ApexPro Telemetry System is intended to provide ECG data via Ethernet to the computer platform for processing. The ApexPro is also intended to provide physiologic data over the Unity network to clinical information systems for display.

Technology: The ApexPro employs the same functional technology as the predicate devices. The system architecture has taken advantage of improvements in signal processing technology as well as advances in RF component technologies to improve performance and level of integration.

Test Summary: The ApexPro complies with the voluntary standards as detailed in Section 9 of this submission. The following quality assurance measures were applied to the development of the system:

- Requirements specification review
- Code inspections
- Software and hardware testing
- Safety testing
- Environmental testing
- Final validation

Conclusion: The results of these measurements demonstrated that the ApexPro System is as safe, as effective, and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 07 2002

Ms. Joelle Neider
Regulatory Affairs Specialist
GE Medical Systems Information Technologies
8200 West Tower Avenue
Milwaukee, WI 53223

Re: K021325
Trade Name: ApexPro Telemetry System
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm
Regulatory Class: Class III (three)
Product Code: MHX
Dated: April 22, 2002
Received: April 26, 2002

Dear Ms. Neider:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

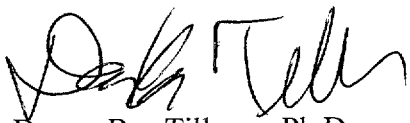
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K021325

510(k) Number (if known): 510(k) filed on April 19, 2002

Device Name: ApexPro Telemetry System

Indications For Use:

The ApexPro Telemetry System is intended for use under the direct supervision of a licensed healthcare practitioner. The system is designed to acquire and monitor physiological data for ambulating patients within a defined coverage area. The system processes this physiological data to detect various ECG arrhythmia events and select physiological parameter limit violations.

The ApexPro Telemetry System is intended to be installed in the hospital or clinical environment in order to provide clinicians with patient physiological data, while allowing for patient mobility. These systems are typically deployed in sub acute care areas in hospitals or clinical sites where patient mobility can enhance the effectiveness of the medical procedures administered.

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K021325